

**SUMMARY OF SAFETY AND EFFECTIVENESS FOR  
DAVIS BAYONET™ ELECTRODES**

K964602

**Intended Use**

Davis Bayonet Electrodes are intended for use in open surgical procedures where monopolar electrosurgical cutting and coagulation are normally used. The Electrodes are intended for use in conventional electrosurgical pencils and chucks as alternatives to other electrosurgical electrodes.

**Product Description**

Davis Bayonet Electrodes are sterile, single use, electrosurgical electrodes with an extended length shaft and an offset bayonet shape to permit the surgeon to see the end of the electrode more easily when performing surgery in cavities or recessed areas. The Electrodes are available with loop, ball, and needle tip configurations.

**Safety and Performance**

**1. Biocompatibility Testing**

The biological safety of the Davis Bayonet Electrodes has been assured through the selection of materials which demonstrate appropriate levels of biocompatibility. The components of the Electrodes have incidental short term contact with patient tissues at the surgical site.

**2. Performance Testing**

The Davis Bayonet Electrodes have been designed to conform with the applicable sections of AAMI HF18, 1993, Electrosurgical Devices, and IEC 601-2-2, 1991-09, Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of High Frequency Surgical Equipment. Performance testing was conducted on representative product.

**Electrical Testing**

Electrode insulation was tested at both low frequency (60Hz) and radio frequency typical of electrosurgical generators. The insulation passed all test requirements.

**Functional Testing**

Functional tests were performed on chicken breast in the laboratory. All electrodes performed properly and no electrode damage occurred at recommended power levels.

**Assembly Testing**

Electrodes assembled properly into Valleylab electrosurgical pencils, and exhibited an appropriate removal force. The force required to separate the electrode tip from the electrode shaft also met performance requirements.

#### Package and Shipping Testing

Packaged product was subjected to environmental conditioning and rigorous vibration and drop testing. No significant damage occurred.

#### Substantial Equivalence

Davis Bayonet Electrodes are substantially equivalent in function and intended use to the following legally marketed devices.

- Valleylab E1000 series Electrodes
- Valleylab E1550 series Electrodes